

REMARKS

Applicant has amended the Claims 1, 3, 4, 9 and 10. Applicant respectfully submits that these amendments to the claims are supported by the application as originally filed and do not contain any new matter. Therefore, the Final Office Action will be discussed in terms of the claims as amended.

The Examiner has rejected the Claims 1-7, 9-13 and 15 as containing new matter and further stating that the original disclosure fails to disclose "isolated" isoflavone aglycone. In reply thereto, Applicant directs the Examiner's attention to page 2, line 4, wherein it describes the isoflavone aglycone as being "produced by extraction and concentration." Applicant respectfully submits that the use of the word "isolated" was meant to indicate this property. In any event, Applicant has amended the claims to indicate that the isoflavone aglycone is "concentrated" and Applicant respectfully submits that such a limitation is within the scope of the application as originally filed and does not contain any new matter. In addition, since this issue was previously presented and argued in Applicant's prior response, Applicant respectfully submits that whether it is "isolated" or "concentrated" does not raise a new issue which would require further consideration and/or search.

The Examiner has rejected the Claims 1-7, 9-13, and 15 under 35 U.S.C. 112, first paragraph, as failing to describe in the specification the invention in such a way as to enable one skilled in the art to which it pertains to make or use the invention.

In reply thereto, Applicant would like to first direct the Examiner's attention to certain case law as set forth below:

In particular, in ex parte Breuer, 1USPQ2d 1906 (Board of Patent Appeals 1986), the court stated:

"in view of applicant's...disclosure describing how to make and use the claimed compounds, including...working examples, we are persuaded that a person having ordinary skill in enabled to practice the claimed invention without undue experimentation."

Still further, in Fiers v. Revel, 984 F.2d 1164 (CAFC 1993), the court stated:

"a specification disclosure which contains a teaching of the manner or process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken

as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein....”

Still further, in Gould v. Quigg, 3 USPQ2D 1302 (CAFC 1987), the court further stated:

“There is no requirement in 35 U.S.C. section 112 or anywhere else in the patent law that a specification convince persons skilled in the art that the assertions in the specification are correct...In examining a patent application, the P.T.O. is required to assume that the specification complies with the enablement provisions of section 112 unless it has ‘acceptable evidence or reasoning’ to suggest otherwise....”

In view of the above decisions and the light shed on the law thereby, Applicant respectfully submits that Applicant’s application clearly teaches how to make Applicant’s invention at pages 8 through 10 thereof and the four examples contained at pages 18-32 of Applicant’s application show one of ordinary skill in the art how to make and use Applicant’s invention and therefore the enablement requirement is met thereby.

In view of the above, therefore, Applicant respectfully requests that the Examiner withdraw this rejection.

The Examiner has rejected the Claims 1-7, 9-13, and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention. In particular, the Examiner states that with respect to the claimed recitation, “stem cell-augmenting” material, and in what sense it “augments” the stem cell, Applicant points to paragraph 4 on page 3 in the specification. However, the paragraph reads “stem cells are augmented by the activity of diadzein,” but does not define in what characteristics the stem cells have been augmented. Hence, the metes and bounds and bounds of the claims are unclear. Still further, it is the Examiner’s opinion that the claims must, under modern claim practice, stand alone to define invention, and incorporation into claims by express reference to the specification and/or drawings is not permitted.

In reply thereto, Applicant directs the Examiner's attention to paragraph on page 3 wherein the Examiner appears to have not entirely quoted Applicant's statement. In particular, at paragraph 4, page 3, it states:

"As a result of further intense research, the inventors completed the present invention upon discovering that stem cells are augmented by the activity (estrogen-like activity) of diadzein."

Still further, Applicant directs the Examiner's attention to the paragraph bridging pages 3 and 4, wherein it states:

"The stem cell-augmenting activity will be described below. The stem cells augmented by the isoflavone aglycone obtained by the present invention of the properties of self-replication and differentiation and corporation;...it appears that the composition of the isoflavone aglycone obtained by the present invention, particularly isoflavone aglycone the components have been concentrated by solvent extraction, comprise large amounts of diadzein..., the main function is the estrogen-like activity of the large diadzein content, resulting in the augmentation of stem cells."

Referring next to page 4, the last five lines of the first full paragraph, it states therein:

"Therefore, the diadzein that is a type of isoflavone aglycone obtained by the present invention has an estrogen-like role and apparently binds with ER to actuate STAT3ER activity and proliferate bone marrow hematopoietic cells. As a result, embryonic stem cells wherein STAT3 is the signal-transmitting substance can also be augmented by the isoflavone aglycone obtained by the present invention."

Still further, Applicant directs the Examiner's attention to the last three lines of the second full paragraph on page 4 of Applicant's application and particularly where it states:

"Estrogen-like activity that does not block the enzyme activity of enzymes that act on cell proliferation factor can be given as the activity of this isoflavone aglycone in terms of augmenting stem cells."

Finally, Applicant directs the Examiner's attention to the four examples contained at pages 18-32 of Applicant's application as clearly describing the activity of Applicant's invention.

Finally, Applicant would like to point out that Applicant has not argued that the specification should be incorporated into the claims. Instead, Applicant has argued that the claims should be read in light of the specification and the disclosure of Applicant's invention and as such Applicant's position is supported by the case law.

In view of the above, therefore, Applicant respectfully submits that the Claims 1-7, 9-13 and 15 comply with the requirements of 35 U.S.C. 112, second paragraph.

Applicant also acknowledges the Examiner's statement that the prior rejection to the Claims 1-6 and 9-12 under 35 U.S.C. 102 as being anticipated by Luksas, et al. is withdrawn.

Applicant also acknowledges the Examiner's statement that the prior rejection of Claims 1-6 and 9-12 under 35 U.S.C. 102 as being anticipated by Groben, et al. is withdrawn.

Still further, Applicant acknowledges the Examiner's statement that the Claims 1-6 and 9-12 is being anticipated by Bojrab, et al. is withdrawn.

The Examiner has rejected the Claims 1-7, 9-13 and 15 under 35 U.S.C. 102 as being anticipated by Takebe, et al. (USP 5,885,632).

Firstly, Applicant would like to point out that the Examiner has further used this same patent to reject Applicant's invention based upon the judicially created doctrine of obviousness-type double patenting and Applicant has filed a terminal disclaimer and the Examiner has withdrawn the rejection under the judicially created doctrine of obviousness-type double patenting. Therefore, Applicant respectfully submits that if the Examiner has once acknowledged that Applicant's claims 1-16 were rejected under the judicially created doctrine of obviousness-type double patenting, the Examiner should not now be able to state that Takebe, et al. discloses each and every element of Applicant's invention as claimed in Claims 1-7, 9-13 and 15.

Still further, Applicant directs the Examiner's attention to Tables 2 and 3, and respectfully submits that neither table discloses that the isoflavone aglycone would be comprised of 70wt% daizein. In particular, Table 2 indicates that the resultant comprises 25 mg of diadzin, 74 mg of diadzein, 53 mg of genistin, and 59 mg of genistein for a total of 211 mg. Accordingly, the weight percentage of diadzein would be approximately 35%, substantially less than Applicant's required 70%. Looking at Table 3, the post amounts are 70 mg of daidzein and 64 mg of genistein for a total of 134 mg. As a result, the percentage of diadzein is approximately 55%. Again, as shown in Table 3, the percentage of diadzein is less than the required 70% by

weight of Applicant's invention. Still further, it may be assumed that other isoflavone aglycone would be produced such as glycitein, and neither Tables 2 nor 3 of Takebe, et al. disclose the existence of such a compound and therefore it may be assumed that the percentages of diadzein are lower.

In view of the above, therefore, Applicant respectfully submits that Claims 1-7, 9-13 and 15 are not anticipated by Takebe, et al.

The Examiner has further rejected the Claims 1-7, 9-13 and 15 under 35 U.S.C. 102 as being anticipated by Takebe, et al. (USP 6,045,819). Again, the Examiner has rejected the Claims 1-16 of Applicant's invention under the judicially created doctrine of obviousness-type double patenting based upon this same art. As such, Applicant respectfully submits that the claims should not be anticipated based upon this art of record for the same reasons stated relative to the '632 patent.

In addition, Applicant respectfully submits that Table 5 of Takebe, et al. '819 also discloses that the resultant products are in the total amount of 211 mg, of which only 74 mg are diadzein. As a result, Applicant respectfully submits that the weight percentage of diadzein is merely 35%. Similarly and as to Table 6, Applicant respectfully submits that the amount of diadzein is only present in an amount of about 55% since there are only 70 mg of diadzein and the total amount of isoflavone aglycones is 134 mg.

In view of the above, therefore, Applicant respectfully submits that Takebe, et al. '819 does not show that the isoflavone aglycone is comprised of at least 70wt% diadzein as is required by Applicant's claims. Therefore, the Claims 1-7, 9-13 and 15 are not anticipated by Takebe, et al. '819.

The Examiner has further rejected the Claims 1-7, 9-13 and 15 under 35 U.S.C. 102 as being anticipated by Takebe, et al. '161. Similarly to previously argued, Applicant respectfully submits the Examiner has applied this same art to reject Applicant's claims under the judicially created doctrine of obviousness-type double patenting, which implies that Takebe, et al. '161 does not disclose each and every element of Applicant's invention.

In addition, Applicant has carefully reviewed Takebe, et al. '161 and respectfully submits that both Tables 4 and 5 disclose that the diadzein is only present in the amounts of 35% and 55% by weight and does not disclose 70% weight diadzein. Therefore, Applicant respectfully submits that Claims 1-7, 9-13 and 15 are not anticipated by Takebe, et al. '161.

Applicant further acknowledges the Examiner's statement that the prior rejection of the Claims 1-7, 9-13 and 15 under 35 U.S.C. 102 is being anticipated by Obata, et al. is withdrawn.

The Examiner has rejected the Claims 1-7, 9-13 and 15 under 35 U.S.C. 102 as being anticipated by Kelly, et al.

Applicant has carefully reviewed Kelly, et al., and respectfully submits that except for the ratios identified in the claims, such ratios are not mentioned anywhere in the description, and particularly not in the disclosure of the invention. The only ratios are given at column 6, lines 6-8, wherein it states:

"It is also preferred that the ratio of genistein and/or its methylated derivative biochanin A to daidzein and/or its methylated derivative formononetin is between 1:2 to 2:1."

In other words, Applicant respectfully submits that Kelly, et al. suggests that the diadzein would be present in an amount from about 30-60%. Still further, Applicant respectfully submits that the Claim 1 is directed towards to "health supplement comprising...a natural occurring phyto-oestrogen selected from any two or more of genistein, diadzein and/or their glycosides." Applicant respectfully submits that this an open-ended claim, and does not claim that the supplement would only contain the particular aglycones mentioned therein. In particular, Applicant respectfully submits that Kelly, et al. states that there are more than 700 isoflavones which are phyto-oestrogens (see column 1, line 50). Still further, Applicant respectfully submits that Claim 13 states that the "phyto-oestrogen comprises genistein:diadzein present in a ratio of about 1:19." Again, this is an open-ended claim which does not limit the components to only genistein or diadzein, and therefore, the total amount of aglycones such as glycosides and glycitein could be substantially higher. Still further, Applicant respectfully submits that the Claim 13 does not define whether the ratio is in terms of weight, volume, etc.

In view of the above, therefore, Applicant respectfully submits that the Claims 1-7, 9-13 and 15 are not anticipated by Kelly, et al.

The Examiner has rejected the Claims 1-7, 9-13 and 15 provisionally under 35 U.S.C. 102 as being anticipated by copending application no. 09/284,935.

Again, Applicant would like to point out that this copending application has also been applied against the claims under the judicially created doctrine of obviousness-type double patenting which is an implication that this application does not disclose each and every element

of Applicant's invention. Still further, Applicant respectfully submits that in a similar manner as the other art cited to Takebe, et al., copending application no. 09/284,935 does not disclose the existence of diadzein in an amount greater than 70wt%. Therefore, Applicant respectfully submits that the Claims 1-7, 9-13 and 15 are not anticipated by copending application no. 09/284,935.

The Examiner has further rejected the Claims 1-7, 9-13 and 15 under 35 U.S.C. 102(f), stating that the Applicant did not invent the claimed subject matter since each of the patents 5,885,632; 6,045,819; and 6,303,161 and copending application no. 09/284,935 contain different inventive entities which invented the same thing. As discussed above, Applicant respectfully submits that each of the cited patents and the copending application do not disclose Applicant's invention. Therefore, Applicant respectfully submits that Claims 1-7, 9-13 and 15 are not properly rejected under 35 U.S.C. 102(f).


In addition, Applicant acknowledges the Examiner's statement that the rejections based on the judicially created doctrine of obviousness-type double patenting has been withdrawn because of the filing of Applicant's terminal disclaimer.

In view of the above, therefore, it is respectfully requested that this Rule 116 Amendment be entered, favorably considered, and the case passed to issue.

Please charge any additional costs incurred by or in order to implement this Rule 116 Amendment or required by any requests for extensions of time to KODA & ANDROLIA DEPOSIT ACCOUNT NO. 11-1445.

Respectfully submitted,

KODA & ANDROLIA

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